

# Consent Process

## Background

---

A fundamental ethical obligation for researchers is to ensure that all persons who participate in their research have had the opportunity to freely consent to take part in the study. In order to freely consent, potential subjects must be given sufficient *information* about the study in a manner that is *understandable* to them so they can make a *voluntary* decision about whether or not they wish to participate. Potential subjects must be adequately informed about the procedures they will be asked to complete, the risks and benefits associated with participation, the voluntary nature of participation, how the information they provide will be used, the measures that will be used to protect their privacy and confidentiality, any costs or compensation related to participation, and whom to contact should they have questions about the study or about their rights as research subjects. This document addresses issues related to the consent process and provides information to guide investigators as they plan their studies.

## Obtaining Consent is a Process

---

Obtaining consent from potential subjects should be an educational process that takes place between the investigator and research subject prior to participation and throughout the study. Although a specific document is typically created to provide subjects with information, asking subjects to read and sign a document is only *one part* of the process. A complete consent process should involve giving potential subjects verbal and written information about the study and allowing sufficient time to consider their options and ask questions about the study before making a decision. Any new information that might affect their willingness to continue as a subject should be shared throughout the course of the study.

## Issues Related to the Consent Process

---

### Consent Must be Given Freely

Deciding whether or not to participate in a research study should be totally at the discretion of the subject. The consent process is not an exercise in persuasion, and situations where explicit or implicit coercion may exist should be avoided. For example, if an investigator has a relationship with potential subjects, particularly an authoritative relationship (e.g., teacher-student; employer-employee; doctor-patient), care must be taken to ensure recruitment methods are not coercive due to the relationship between parties.

Potential subjects must be informed that no penalty or loss of benefit will incur should they choose not to participate. Any potential concerns a subject might have should be addressed. For example, employees should be informed that there will be no effect on their employment status based upon their participation in the study.

Consent is a legal concept—only legally competent adults can consent to participate in a study. Children (individuals legally deemed to be a minor) or adults who are not competent (e.g., cognitively impaired persons) must **assent** (affirmatively agree) to participate, but **consent** must be obtained from a parent or legally authorized representative. Provisions must be made in the consent process to obtain *both* consent and independent, non-coerced assent when subjects are not legally competent adults. In cases where subjects cannot give assent (e.g., very young children or significantly cognitively impaired persons), the IRB can approve a research protocol that does not include obtaining assent. Please see the document entitled “Assent Process” for more information.

If *either* consent or assent is refused, the subject should not be enrolled in the study.

## Consent Must be Based on Understanding

Information related to the study must be provided to subjects in a manner that they can understand. This manner will differ based upon the population being studied. For example, subjects who do not speak English must be provided information in a language they understand. A verbal explanation should be given to subjects who cannot read or have limited reading ability. The information must be presented in language that is understandable to a lay person. Scientific jargon is typically inappropriate; ordinary language is better. Documents given to adult or older teenaged subjects should be written at the 7<sup>th</sup> or 8<sup>th</sup> grade reading level; simpler explanations should be provided to younger children.

## Consent Must be Active

A common misconception about the consent involves the use of “passive consent,” sometimes referred to as the “backpack method,” where subjects are assumed to have agreed to consent in the absence of a response to “opt out.” For example, sending a letter home with students that is used to inform parents of a research project taking place in a school and giving them the opportunity to object if they do not wish for their child to participate is considered passive consent. Passive consent is not supported in the regulations and cannot be approved by the IRB as a valid consent process unless a waiver of consent is requested and approved (see [Waivers or Alterations of Consent](#)).

## Consent Must be Documented\*

Part of the consent process involves providing written information to subjects in an “informed consent document.” The purpose of this document is to provide subjects with written information for their future reference *and* to document the fact that the process of consent occurred *prior* to subjects’ participation in the research. As part of the overall consent process, the informed consent document

- Is typically signed after the investigator has verbally explained the purpose and procedures involved in the study, answered any questions subjects have, and provided additional information (if needed) to allow subjects to make an informed decision;
- Must be written in language understandable to the subjects and formatted to ensure readability (e.g., large font for elderly subjects);
- Must include [all elements that are required by regulations](#); the IRB has developed a [template](#) that can be used by investigators to ensure necessary elements are included;
- Must include all research personnel who will be involved in the informed consent process named as members of the research team at the beginning of the document;
- In general, must include signature lines with dates for the subject and the person who obtained consent (e.g., the investigator); signature lines for parents, legal guardians, or legally authorized representatives, or for documentation of assent, should be added if appropriate for the study;
- Must be signed *and* dated **before** data collection begins;
- Must be the document approved by the IRB as indicated by a current IRB approval stamp;
- Must be updated to include any modifications to the study procedures or changes in the level of risk to participants; the IRB may require previously enrolled subjects to sign a new document if increased risks have been identified;
- Must be reviewed at the time of continuing review (if applicable).

Because the informed consent document serves as documentation of the consent process, the following procedures must be followed:

- Subjects must be provided with a copy of the complete document for their records.
- The investigator must keep the original signed copies of the entire document (not just the signature page) as records for three years after the study is officially closed unless a waiver of documentation of consent is granted by the IRB.

**\*NOTE:** See [Waivers or Alterations of Consent](#) guidance for information about requesting IRB approval of a waiver of documented consent.

## Common Problems

---

### Common Problems with the Consent *Process*

- Subjects are given the consent document to sign with little or no interaction with investigators or little or no time to consider participation or ask questions. Remember, informed consent is a *process*, not just a document!
- The consent process does not follow the IRB approved procedures.
- Subjects are enrolled prior to obtaining consent or assent, or a “passive consent” method is used. Active, affirmative consent and assent (if applicable) must be obtained prior to enrollment of the subject in the study.
- Consent documents are not signed by participants. Unless a waiver of documentation is granted, consent documents must be signed.
- Consent documents are not dated by participants.
- Consent documents are not signed by investigators when a signature line for investigators has been included.
- Subjects are not given a copy of the complete document for their records. Subjects should be given a copy of the complete consent document to keep.
- Investigators do not retain the complete signed documents for three years’ time. Regulations require that consent documents be retained for three years following the close of the study.

### Common Problems with the Consent *Document*

- It includes scientific or technical terms or jargon that subjects do not understand. Be sure to use clear, ordinary terms that a lay person will understand.
- It does not include a complete or clear explanation of study procedures, possible risks, the voluntary nature of participation, or other required elements. Be sure to include all required elements and complete explanations for each.
- It is written at a reading level that is too high for most subjects. Documents should be written at no higher than an 8th grade reading level. (Most word processing programs can determine readability levels.)
- It is difficult to read. Font size should be at least 11 point (much larger if subjects are likely to have vision problems); logical headings, subheadings, and sufficient white space should be utilized to ensure readability.
- It includes unnecessary signature lines (e.g., parent/guardian signature line included when subjects are not minors; signature lines are included when a waiver of documentation of consent has been granted). Include only the signature lines that are appropriate for your study.

- It is inconsistent with the procedures discussed in the protocol (i.e., the Human Subjects Review form). Be sure that the methods and procedures described in the consent document accurately reflect the study and are consistent with the methods and procedures described in the Human Subjects Review form.

#### Document History

---

---

*Created: August 2007*

---

---